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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two approved new animal drug applications (NADA's) from Wendt Laboratories, Inc., to First Priority, Inc.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Norman J. Turner, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0214.

SUPPLEMENTARY INFORMATION: Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011, has informed FDA that it has transferred to First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, ownership of, and all rights and interests in NADA 48–646 for Therazone Injection and NADA 48–647 for Therazone Tablets. Accordingly, the agency is amending the regulations in 21 CFR 520.1720a and 522.1720 to reflect the transfer of ownership.

In addition, First Priority, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A), because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for ''First Priority, Inc.'' and in the table in paragraph (c)(2) by numerically adding an entry for ''058829'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	* *
First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123	058829
* * * * *	* *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * * *
058829	First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123.
* * *	* * * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1720a [Amended]

4. Section 520.1720a *Phenylbutazone tablets and boluses* is amended in paragraph (b)(3) by removing ''015579'' and adding in its place ''058829''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1720 [Amended]

6. Section 522.1720 *Phenylbutazone injection* is amended in paragraph (b)(1) by removing ''015579'' and adding in its place ''058829''.

Dated: 2/09/01
February 9, 2001.

Claire M. Lathers,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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